

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

ROCHESTER DRUG CO-OPERATIVE,
INC., on behalf of itself and all others
similarly situated,

Plaintiff,

v.

ALLERGAN PLC; IMPAX
LABORATORIES, INC.; LANNETT
COMPANY, INC.; MYLAN INC.;
MYLAN PHARMACEUTICALS INC.;
PAR PHARMACEUTICALS COMPANIES
INC.; SUN PHARMACEUTICAL
INDUSTRIES, INC.; and WEST-WARD
PHARMACEUTICALS CORP.,

Defendants.

Civil Action No.

CLASS ACTION

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

TABLE OF CONTENTS

| | | |
|------|--|----|
| I. | INTRODUCTION | 1 |
| II. | JURISDICTION AND VENUE | 5 |
| III. | PARTIES | 6 |
| A. | Plaintiff | 6 |
| B. | Defendants | 6 |
| IV. | UNIDENTIFIED CO-CONSPIRATORS..... | 7 |
| V. | FACTUAL ALLEGATIONS | 8 |
| A. | Overview of Generic Drug Market..... | 8 |
| 1. | Generic drugs lead to lower prices | 8 |
| 2. | How generic drugs come to market..... | 11 |
| B. | Generic Doxycycline Market and Pricing Information | 12 |
| 1. | Branded Doxycycline | 13 |
| 2. | Generic Doxycycline | 13 |
| 3. | Concentration in the Market for Generic Doxycycline | 14 |
| 4. | Generic Doxycycline Prices Soar | 14 |
| C. | Generic Digoxin Market and Pricing Information..... | 18 |
| 1. | Branded Digoxin (Lanoxin)..... | 19 |
| 2. | Generic Digoxin | 19 |
| 3. | Concentration in the Market for Generic Digoxin..... | 20 |
| 4. | Generic Digoxin Prices Soar | 21 |
| D. | Defendants’ Coordination and Collusion on Generic Drug Pricing | 25 |
| E. | Defendants’ Claims that Rising Costs Justified the Price Increases Were Pretextual..... | 35 |
| F. | Government Investigations | 36 |

| | |
|--|----|
| 1. Congressional Investigation into Generic Drug Pricing | 36 |
| 2. Federal and State Antitrust Investigations into Defendants’ Generic Drug Pricing | 39 |
| VI. THE GENERIC DRUG MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION | 43 |
| VII. CLASS ACTION ALLEGATIONS | 45 |
| VIII. ANTITRUST INJURY | 47 |
| IX. CLAIM FOR RELIEF | 47 |
| X. PRAYER FOR RELIEF | 49 |
| XI. DEMAND FOR JURY TRIAL | 49 |

Plaintiff Rochester Drug Co-Operative, Inc. (“RDC” or “Plaintiff”) brings this class action, on behalf of itself and all others similarly situated, against Allergan plc (formerly Actavis plc); Impax Laboratories, Inc.; Lannett Company, Inc.; Mylan Inc.; Mylan Pharmaceuticals Inc.; Par Pharmaceutical Companies Inc.; Sun Pharmaceutical Industries, Inc.; and West-Ward Pharmaceuticals Corp., (collectively, “Defendants”), based upon personal knowledge as to facts pertaining to itself, and upon information and belief as to all other matters, and alleges as follows:

I. INTRODUCTION

1. Generic drugs are a key component of the healthcare system. However, in recent years, the pricing on certain common generic drugs has skyrocketed. Normal market forces do not explain these rapid price increases. Instead, manufacturers have improperly entered a scheme to hike prices far beyond what they would be in a competitive market.

2. Doxycycline and digoxin are two generic drugs that exemplify this issue. Both doxycycline and digoxin are commonly prescribed medications. Doxycycline is a broad-spectrum antibiotic. Digoxin is prescribed for the treatment of atrial fibrillation and other cardiac ailments. Their common use has led to both drugs being designated as “essential medicines” by the World Health Organization (“WHO”).¹ According to the WHO:

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.²

¹ WHO Model List of Essential Medicines – 19th List (Apr. 2015 and amended Aug. 2015), *available at* http://www.who.int/selection_medicines/committees/expert/20/EML_2015_FINAL_amended_AUG2015.pdf?ua=1.

² WHO, Essential Medicines, *available at* http://www.who.int/topics/essential_medicines/en/.

3. Neither doxycycline nor digoxin is new. Doxycycline was developed in the mid-20th century and was on the United States market by December 1967. Digoxin is even older, with the therapeutic properties of the drug having been known since the late 18th century. Neither drug compound is protected by any patents.

4. Generic versions of both drugs have been on the market for at least two decades and, for much of that time, have had relatively low prices. This is because the presence of generic drugs usually results in vigorous price competition, benefiting consumers and direct purchasers such as Plaintiff.

5. Recently, however, both drugs have experienced unprecedented and massive increases in price. Specifically, after October 2012 the price of doxycycline increased over 8000%, and after October 2013 the price of digoxin increased over 800%.

6. These price hikes were not the result of competitive market forces; instead, they were the product of Defendants' conspiracy to fix, raise, maintain, and stabilize the prices of, as well as allocate customers and markets for, these products. Defendants orchestrated their conspiracy through earnings calls with industry analysts and other private and public communications and meetings such as trade association meetings held by the Generic Pharmaceutical Association ("GPhA"). Given the number of competitors and the high barriers to entry in the markets for doxycycline and digoxin tablets these markets were ripe for collusion. Defendants recognized this and engaged in anticompetitive actions that allowed them to sustain their unlawful supracompetitive pricing.

7. Doxycycline and digoxin are likely just the tip of the iceberg. There have been a number of large price hikes observed across a number of other generic drugs manufactured by these Defendants. Defendants' price increases have drawn the attention of the government

enforcers, members of Congress, the press, and drug purchasers.³ The Department of Justice (“DOJ”) and the Connecticut Attorney General’s Office issued subpoenas to Defendants Impax, Lannett, and Par seeking documents and testimony concerning the pricing of digoxin tablets. Defendants Allergan, Lannett, Mylan, and Par received similar subpoenas in connection with their pricing of doxycycline. The DOJ subpoenas to these companies arise from a grand jury proceeding in the Eastern District of Pennsylvania. The DOJ has also subpoenaed information relating to a variety of other generic drugs. According to the Policy and Regulatory Report, “this [DOJ] investigation could become the next auto parts investigation . . . [which is] the DOJ’s largest prosecution to date . . . [w]ith untold numbers of different generic drugs on the market, it may be possible for prosecutors to move from one drug to another in a similar cascading fashion.”⁴

8. The DOJ’s 2014 investigation followed a congressional hearing and investigation prompted by the National Community Pharmacists Association’s (“NCPA”) January 2014 correspondence to the U.S. Senate Health Education Labor and Pensions (“HELP”) Committee and the U.S. House Energy and Commerce Committee requesting hearings on the significant spike in generic drug pricing.⁵ The NCPA’s news release states:

³ See, e.g., Press Release, U.S. House and Senate, Ranking Member Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs (Oct. 2, 2014) (noting large and unusual price increases on doxycycline, digoxin, albuterol sulfate, glycopyrrolate, divalproex sodium ER, pravastatin sodium, neostigmine methylsulfate, and benazepril/hydrochlorothiazide), *available at* <http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file>.

⁴ Policy and Regulatory Report, *DOJ believes collusion over generic drug prices widespread* (June 26, 2015), *available at* <http://www.mergermarket.com/pdf/DoJ-Collusion-Generic-Drug-Prices-2015.pdf>.

⁵ National Community Pharmacists Association Press Release, *Generic Drug Price Spikes Demand Congressional Hearing, Pharmacists Say* (Jan. 8, 2014), *available at* <http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say>.

Pharmacy acquisition prices for many essential generic drugs have risen by as much as 600%, 1,000% or more, according to a survey of more than 1,000 community pharmacists conducted by NCPA. The same survey found that patients are declining their medication due to increased co-pays (or total costs for the uninsured) and that the trend has forced more seniors into Medicare's dreaded coverage gap (or "donut hole") where they must pay far higher out-of-pocket costs.

9. Further, NCPA's survey of community pharmacists found the following:

- 77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price.
- 86% of pharmacists said it took the pharmacy benefit manager ("PBM") or other third-party payer between two and six months to update its reimbursement rate (but not retroactively).
- Patients may be referred to other pharmacies because the community pharmacy could not absorb losses of \$40, \$60, \$100 or more per prescription filled, due to inadequate and/or outdated reimbursement rates.
- 84% of pharmacists said the unsustainable losses per prescription are having a "very significant" impact on their ability to remain in business and to continue serving patients.

10. In addition to the DOJ's and the Connecticut Attorney General's investigations, members of Congress have written letters to each Defendant requesting information concerning their sales of doxycycline and digoxin.

11. Defendants have collectively and unlawfully colluded to restrain and/or eliminate competition by engaging in an anticompetitive conspiracy designed to raise prices and foreclose competition in at least the markets for generic digoxin and doxycycline in the United States, in violation of Section 1 of the Sherman Act. This misconduct enabled each and every Defendant to overcharge direct purchasers for the generic drugs.

12. As a result of Defendants' scheme to fix, raise, maintain, and stabilize the price of doxycycline and digoxin, direct purchasers, such as Plaintiff, have paid and continue to pay supracompetitive prices.

II. JURISDICTION AND VENUE

13. This action arises under section 1 of the Sherman Act, 15 U.S.C. § 1 and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit and reasonable attorneys' fees for the injuries sustained by RDC and members of the Class (defined below) resulting from Defendants' conspiracy to restrain trade in the United States. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

14. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the Class Period, the Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the alleged activity affected interstate trade and commerce discussed below has been carried out in this District.

15. During the Class Period, Defendants sold and shipped generic drugs in a continuous and uninterrupted flow of interstate commerce, which included sales of generic digoxin and doxycycline in the United States, including in this District. Defendants' conduct had direct, substantial, and reasonably foreseeable effects on interstate commerce in the United States, including in this District.

16. This Court has personal jurisdiction over each Defendant because, *inter alia*, each Defendant: (a) transacted business throughout the United States, including in this District; (b) participated in the selling and distribution of generic digoxin and doxycycline throughout the United States, including in this District; (c) had and maintained substantial contacts with the United States, including in this District; or (d) was engaged in an unlawful conspiracy to inflate the prices for generic doxycycline and digoxin that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

III. PARTIES

A. Plaintiff

17. Plaintiff Rochester Drug Co-Operative, Inc. (“RDC”) is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business at 50 Jet View Drive, Rochester, New York 14624. During the Class Period, as defined below, RDC purchased generic digoxin and doxycycline at supracompetitive prices thereby suffering injury to its business and property.

B. Defendants

18. Defendant Allergan plc (“Allergan” – formerly Actavis plc) is a public limited company incorporated under the laws of Ireland with its principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. Allergan’s United States headquarters is located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

19. Defendant Impax Laboratories, Inc. (“Impax”) is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

20. Defendant Lannett Company, Inc. (“Lannett”) is a Delaware corporation with its principal place of business at 9000 State Road, Philadelphia, PA 19136.

21. Defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

22. Defendant Mylan Pharmaceuticals Inc. is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

23. Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. are collectively referred to as “Mylan.”

24. Defendant Par Pharmaceutical Companies, Inc. (“Par”) is a Delaware corporation with its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977. In September 2015, Endo International plc completed its acquisition of Par.

25. Defendant Sun Pharmaceutical Industries, Inc. (“Sun”) is an Indian corporation with its principal place of business located at 270 Prospect Plains Road, Cranbury, New Jersey 08512.

26. Defendant West-Ward Pharmaceuticals Corp. (“West-Ward”) is a New Jersey corporation with its principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724. West-Ward is a subsidiary of Hikma International Pharmaceuticals plc.

27. Defendants Allergan, Impax, Lannett, Mylan, Par, Sun, and West-Ward are collectively referred to as “Defendants.”

28. All of Defendants’ actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants’ various officers, agents, employees, or other representatives while actively engaged in the management of Defendants’ affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, or with the actual, apparent, or ostensible authority of Defendants.

IV. UNIDENTIFIED CO-CONSPIRATORS

29. Various other persons, firms, entities and corporations, not named as Defendants in this Complaint, have participated as co-conspirators with Defendants in the violations alleged herein, and have aided, abetted, and performed acts and made statements in furtherance of the conspiracy.

30. The true names and capacities of these unidentified co-conspirators, whether individual, corporate, associate, or representative, is unknown to Plaintiff at this time. Plaintiff

may amend this Complaint, as necessary, to allege the true names and capacities of additional co-conspirators as their identities become known through discovery.

31. At all relevant times, other persons, firms, and corporations, referred to herein as “co-conspirators,” the identities of which are presently unknown, have willingly conspired with Defendants in their unlawful scheme as described herein.

32. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

V. FACTUAL ALLEGATIONS

A. Overview of Generic Drug Market

1. Generic drugs lead to lower prices

33. Generic drugs typically provide consumers with a lower cost alternative to brand drugs while providing the same treatment. Specifically:

A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or “therapeutic equivalence,” of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as “therapeutically equivalent” can be expected to have equal effect and no difference when substituted for the brand name product.⁶

⁶ FDA, Generic Drugs: Questions and Answers, *available at* <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>.

34. Further, “[d]rug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.”⁷

35. Generic versions of brand drugs are priced significantly below the brand versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand product unless the doctor has indicated that the prescription for the brand product must be dispensed as written. States adopted substitution laws following the federal government's 1984 enactment of the Hatch-Waxman Act (discussed in more detail below).

36. The FDA has recognized that “[g]eneric competition is associated with lower drug prices[.]”⁸ A Federal Trade Commission study reached the same conclusion finding that in a “mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices.”⁹ Economic literature in the healthcare market further confirms that competition by generic products results in lower prices for consumers. In the period before generic entry, a brand drug commands 100% of the market share for that drug and the brand manufacturer can set the price without the impact of competitive market forces. Once the first generic enters the market, however, a brand drug rapidly loses sales, on average 90% within a year.¹⁰ As more generic manufacturers enter the market, prices for generic versions of a drug predictably will

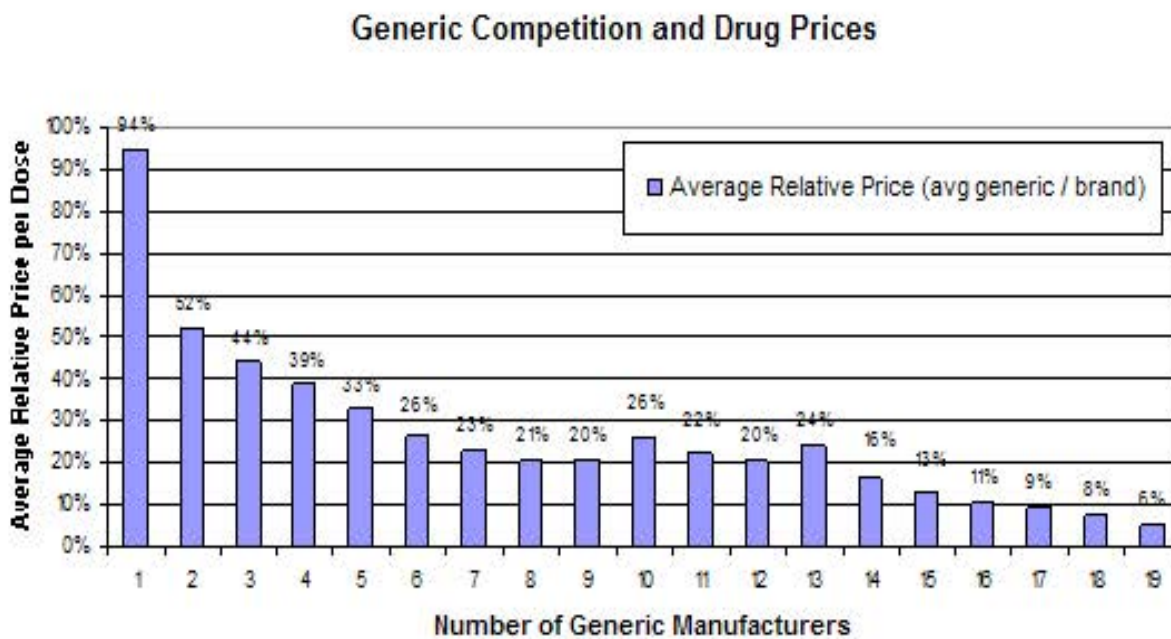
⁷ *Id.*

⁸ FDA, Generic Competition and Drug Prices, *available at* <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

⁹ FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010), *available at* <https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff>.

¹⁰ *Id.*

continue to decrease because of competition among the generic manufacturers, and the loss of sales volume by the brand drug to the corresponding generic accelerates as more generic options are available to purchasers:¹¹



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

37. A mature generic market, such as the markets for doxycycline and digoxin, has several generic competitors. Due to the fact that each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers.¹² Over time, generics' pricing nears the generic manufacturers' marginal costs.

¹¹ See, e.g., Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, HEALTH AFFAIRS, 26, no. 3 (2007):790-799.

¹² See, e.g., FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at 17 (Aug. 2011) (“[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price.”); Congressional Budget Office, “How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry” (July 1998).

38. Generic competition usually enables purchasers to (a) purchase generic versions of the brand drug at a substantially lower price than the brand drug, and/or (b) purchase the brand drug at a reduced price. Generic competition to a single blockbuster brand drug product can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and federal governments, and others. Indeed, one study found that the use of generic medicines saved the United States healthcare system \$254 billion in 2014 alone, and \$1.68 trillion between 2005 and 2014.¹³

2. How generic drugs come to market

39. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application (“NDA”). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. § 355(a), (b).

40. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.¹⁴ Hatch-Waxman allows a manufacturer seeking approval to sell a generic version of a brand drug to file an Abbreviated New Drug Application (“ANDA”). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer’s NDA, and must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent

¹³ Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.*, at 1 (2015), available at http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

¹⁴ See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

and bioequivalent (together, “therapeutically equivalent”) to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an “AB” rating.

41. Most drug companies that want to introduce a generic drug to the market file an ANDA with the FDA’s Center for Drug Evaluation and Research, Office of Generic Drugs. The only exception is for so-called “authorized generics,” which are generics launched under the brand company’s NDA but typically priced like other generics.

42. Generic drugs that are bioequivalent to a brand drug (sometimes called the “Reference Listed Drug” or “RLD”) are assigned a Therapeutic Equivalence Code (“TE Code”). An oral generic drug product will be coded “AB” if bioequivalence is demonstrated. The purpose of this coding is to allow users to determine whether the FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products and to provide information on the basis of the FDA’s evaluations. Thus, generic drugs that are AB-rated to the brand share the same safety and efficacy characteristics and are the same dosage size and form.

B. Generic Doxycycline Market and Pricing Information

43. Generic doxycycline is a tetracycline antibiotic prescribed to patients for the treatment of a variety of bacterial infections, including acne, urinary tract infections, eye infections, Lyme disease, intestinal infections, sexually-transmitted diseases, and gum disease, among others.

44. Doxycycline monohydrate has been prescribed since 1967. Doxycycline hyclate is a variation of doxycycline monohydrate and entered the market in 1985. Doxycycline hyclate and doxycycline monohydrate have the same active ingredient. Unless otherwise indicated,

“doxycycline” refers herein to doxycycline monohydrate and doxycycline hyclate in tablet or capsule form.

1. Branded Doxycycline

45. Branded versions of doxycycline are produced by Pfizer Inc., Aqua Pharmaceuticals LLC, and Fougera Pharmaceuticals Inc., among others.

46. Pfizer developed and manufactured Vibramycin and Vibra-Tabs. Vibramycin is a capsule form of doxycycline hyclate. Vibra-Tabs is a tablet form of Vibramycin. Pfizer received FDA approval for Vibramycin (NDA 050007) on December 5, 1967 and received FDA approval for Vibra-Tabs (NDA 050533) on January 15, 1980.

47. Aqua developed and manufactured Monodox. Monodox is a capsule version of doxycycline monohydrate. Aqua received FDA approval for Monodox (NDA 050641) on December 29, 1989.

48. PharmaDerm, a division of Fougera, manufactures branded versions of Adoxa. Adoxa is a version of doxycycline monohydrate that comes in both capsule and tablet form.

2. Generic Doxycycline

49. Allergan, Lannett, Par, West-Ward and Mylan dominate the market for generic doxycycline.

50. Allergan manufactures generic versions of Vibramycin, Vibra-Tabs, and Monodox (capsule form). Allergan’s generic version of doxycycline first entered the market in 1982.

51. Lannett manufactures generic versions of Adoxa (tablet form). Lannett launched its generic versions of doxycycline in December 2005.

52. Mylan manufactures generic versions of Adoxa (capsule and tablet forms) and Vibra-Tabs. Mylan’s generic versions of doxycycline first entered the market in 1982.

53. Par manufactures generic versions of Adoxa and Monodox (both capsule and tablet forms). Par launched its generic versions of Monodox in 2000 and generic versions of Adoxa in December 2005.

54. Sun manufactures generic versions of Vibramycin, Vibra-Tabs, and Monodox (capsule form). Sun acquired the rights for doxycycline through its acquisition of URL Pharma, Inc.'s generic business from Takeda Pharmaceutical Company Limited in December 2012. Sun also acquired the rights to manufacture doxycycline monohydrate as part of Sun's acquisition of Ranbaxy Laboratories Limited.

55. West-Ward manufactures generic versions of Vibramycin and Vibra-Tabs. West-Ward launched its generic versions of doxycycline in 2003.

56. Impax manufactures generic versions of Adoxa. Impax launched its generic of Adoxa in February 2011.

3. Concentration in the Market for Generic Doxycycline

57. At one point there were over 20 manufacturers of generic doxycycline. However, over the past decade, the number of generic manufacturers producing doxycycline has steadily dropped.

58. This reduction in the number of generic manufacturers increased concentration in the doxycycline market, rendering the market ripe for price coordination and Defendants' conspiracy to fix, raise, maintain, and stabilize prices for doxycycline.

4. Generic Doxycycline Prices Soar

59. The prices of doxycycline have dramatically increased over the past few years. For example, the *Los Angeles Times* reported that in December 2012, an individual who

purchased doxycycline at CVS paid \$4.30 for 60 pills.¹⁵ Three months later, in February 2013, the price for the same quantity of doxycycline had jumped to \$165.16.¹⁶ Pembroke Consulting, a research firm, found that prices of doxycycline hyclate rose over 6,350% between November 2012 and November 2013.¹⁷

60. Further evidence of these staggering price increases for doxycycline was presented by Dr. Stephen Schondelmeyer, Director of the PRIME Institute at the College of Pharmacy of the University of Minnesota in testimony before the U.S. Senate.¹⁸ Dr. Schondelmeyer found that generic doxycycline hyclate prices were generally stable prior to October 2012. Dr. Schondelmeyer tracked Average Wholesale Prices (“AWP”), Wholesale Acquisition Costs (“WAC”), and retail prices for doxycycline hyclate manufactured by West-Ward. West-Ward’s AWP’s for doxycycline hyclate held steady at around \$2.50 per day, from January 2005 to the beginning of October 2012. Retail prices during that period held steady at \$0.50 per day. Similarly, WAC held steady at around \$0.25 per day during that same period.

61. According to an October 2014 U.S. Senate fact sheet on generic drug price increases, the average market price of doxycycline hyclate (bottle of 500, 100 mg tablets) increased from \$20.00 in October 2013 to \$1,849.00 in April 2014, an average percentage increase of over 8000%.¹⁹

¹⁵ David Lazarus, *When a drug costs 30 times what it once did*, LOS ANGELES TIMES (Mar. 7, 2013), available at <http://articles.latimes.com/2013/mar/07/business/la-fi-lazarus-20130308>.

¹⁶ *Id.*

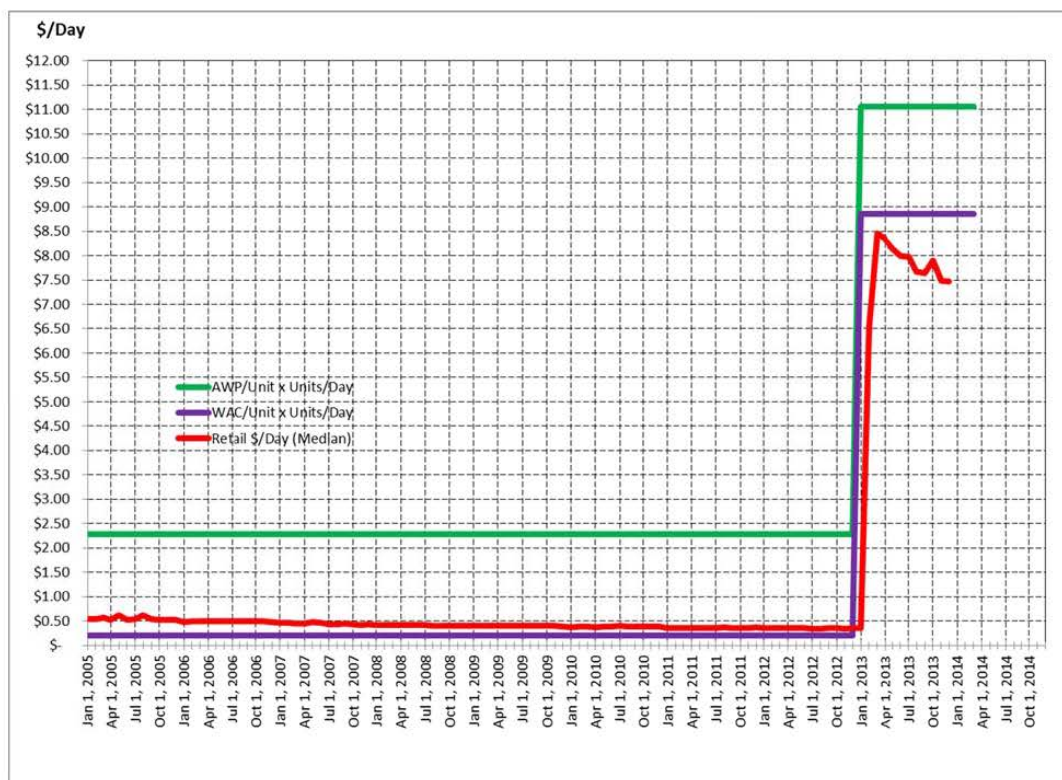
¹⁷ Victoria Colliver, *Prices soar for some generic drugs*, SFGATE (Jan. 1, 2014), available at <http://www.sfgate.com/health/article/Prices-soar-for-some-generic-drugs-5105538.php>.

¹⁸ Statement of Stephen W. Schondelmeyer before the Senate Committee on Health, Education, Labor and Pensions (HELP), *Why Are Some Generic Drugs Skyrocketing in Price?* (Nov. 20, 2014) (“Schondelmeyer Statement”), available at <http://www.help.senate.gov/imo/media/doc/Schondelmeyer.pdf>.

¹⁹ U.S. Senate fact sheet on generic drug price increases, available at <http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file>.

62. For example, West-Ward's AWP pricing for generic doxycycline went from under \$2.50 per day for 100 mg doxycycline hyclate capsule therapy to over \$11 per day by January 2013.²⁰ Retail prices exhibited a similarly large increase, jumping to \$8.50 per day and WAC prices also increased to nearly \$9.00 per day.²¹

Figure 11. Doxycycline Hyclate 100 mg Capsule (West-Ward) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)



63. At all times during the Class Period, there were at least three or more separate manufacturers of generic doxycycline. Under the well-accepted economics of generic competition, when there are that many generic versions of a drug available, all of which by definition are equally substitutable, prices should remain at highly competitive, historic levels, and would not increase as they did here, absent collusion.

²⁰ See Schondelmeyer Statement.

²¹ *Id.*

64. The pricing of each of the Defendant sellers of doxycycline, Allergan, Impax, Lannett, Mylan, Sun and Par increased similarly over the same time period, with average prices of doxycycline increasing dramatically and unjustifiably starting in mid-October 2012.

65. These jumps in price for doxycycline were not simply the product of one rogue doxycycline manufacturer. A rogue manufacturer's supracompetitive pricing would have quickly resulted in a dramatic loss of market share because other generic doxycycline manufacturers would have taken away that manufacturer's sales and market share with competing lower-priced generic doxycycline products. Rather, these supracompetitive prices were the product of a conspiracy among Defendants to raise, maintain, and stabilize the prices of doxycycline to purchasers in the United States.

66. Defendants' own public statements are evidence of such a scheme. For example, in commenting on West-Ward's decision to increase the price of doxycycline over 3,500%, Hikma (West-Ward's parent) CEO, Said Darwazah, incredulously stated in an August 2013 interview that West-Ward was "'forced' to raise prices because its competitors raised theirs."²² Mr. Darwazah's explanation defies economic rationality because an increase in price by competitors did not compel a matching price rise by West-Ward; to the contrary, it provided West-Ward an opportunity to maintain lower prices, or even cut them, to gain market share at the expense of its competitors. However, West-Ward did not do so because it was conspiring with the other Defendants to fix and raise the prices of doxycycline.

²² Alan Katz, *Surprise! Generic-Drug Prices Spike*, BLOOMBERG BUSINESS (Dec. 12, 2013), available at <http://www.bloomberg.com/bw/articles/2013-12-12/generic-drug-prices-spike-in-pharmaceutical-market-surprise>.

67. Defendants' adherence to their price-fixing scheme generated considerable profits. In March 2014, Hikma, West-Ward's parent, announced that revenues from its generic products increased 158% to \$268 million, "reflecting very strong doxycycline sales."²³

68. Sun similarly reported in September 2015 and February 2016 investor presentations that a key driver of its sales through the period 2012 through 2014 was doxycycline, which it described as a "low competition product" in the United States – a notable description given that it is a generic product in a mature generic market.²⁴ In September 2013, Sun reported that its subsidiary URL "had undertaken price hikes in March" and that as a result of these price increases, Sun estimated that "\$60-80 million (of \$128 million in total revenue for URL estimated for FY[20]14) to come from [doxycycline], with operating margins in the range of 50-55 per cent."²⁵

C. Generic Digoxin Market and Pricing Information

69. Generic digoxin is a prescription drug used to treat heart failure and atrial fibrillation. Digoxin is a purified cardiac glycoside derived from *Digitalis lanata*, or the foxglove plant, and was first described in medical literature in 1785.

70. Prior to July 26, 2002, many drug manufacturers produced and sold digoxin tablets. Because digoxin is a drug that was available before the passage of the 1938 Federal Food, Drug, and Cosmetic Act, digoxin was marketed outside of the normal NDA-ANDA

²³ Press Release, Hikma delivers an excellent performance in 2013 with Group revenue growth of 23% and EPS up 111%; Hikma expects continued growth in 2014 (Mar. 12, 2014), *available at* <http://www.hikma.com/~media/Files/H/Hikma/Attachments/pdf/news/corporate/prel-res-pr-12032014.pdf>.

²⁴ Sun Pharma, Creating Lasting Value – Investor Presentation (Feb. 2016), at 47, *available at* [http://www.sunpharma.com/sites/all/themes/sunpharma/images/annual/IR%20Presentation%20June%202016%20\(USD\).pdf](http://www.sunpharma.com/sites/all/themes/sunpharma/images/annual/IR%20Presentation%20June%202016%20(USD).pdf).

²⁵ Ujjval Jauhari, *Sun Pharma's prospects remain bright*, BUSINESS STANDARD (Sept. 12, 2013), *available at* http://www.business-standard.com/article/markets/sun-pharma-s-prospects-remain-bright-113091200894_1.html.

regulatory process. As a result, numerous manufacturers produced and marketed digoxin tablets, subject only to the requirements of the former 21 C.F.R. 310.500, “which established conditions for marketing digoxin products for oral use (tablets and elixir).” However, subsequent FDA rule-making, effective on July 26, 2002, required manufacturers of digoxin tablets to submit NDAs or ANDAs for FDA approval.

1. Branded Digoxin (Lanoxin)

71. On September 30, 1993, GlaxoSmithKline (“GSK”) filed an NDA for the approval of digoxin tablets under the brand name Lanoxin.

72. GSK’s NDA was approved on September 30, 1997 for 0.125 mg and 0.25 mg tablets. Swiss drug manufacturer Covis Pharmaceuticals, Inc. purchased the rights to Lanoxin on December 22, 2011. On April 1, 2015, Covis and its assets—including its rights to Lanoxin were acquired by Concordia Healthcare Corporation.

2. Generic Digoxin

73. Generic digoxin is substituted for the brand drug, Lanoxin. Because GSK’s Lanoxin was not protected by any patents, generic competitors were able to enter the market shortly after GSK began marketing Lanoxin.

74. One of the first generics to file an ANDA in connection with generic Lanoxin was Amide Pharmaceuticals, Inc. (“Amide”). Amide filed ANDA 040282 on October 21, 1997, seeking approval for digoxin tablets. The FDA granted final approval on December 23, 1999. Amide and Mylan—through Mylan’s wholly-owned subsidiary Bertek Pharmaceuticals—entered into a distribution agreement, whereby Mylan distributed Amide’s approved digoxin tablets under the name “Digitek.”

75. The next generic to file an ANDA for generic Lanoxin was Jerome Stevens. Jerome Stevens filed ANDA 76268 on October 29, 2001, seeking approval for digoxin tablets.

The FDA granted final approval on July 26, 2002. In March 2004, Jerome Stevens entered into a 10-year exclusive distribution agreement with Lannett, whereby Lannett became the exclusive seller of Jerome Stevens' digoxin tablets. In August 2013, this exclusive distribution deal was renewed for another five years.

76. At least four other generic manufacturers entered the market for digoxin tablets after Lannett, including: (a) Sun, which received approval for ANDA 076363 on January 31, 2003; (b) West-Ward, which received approval for ANDA 077002 on October 30, 2007; (c) Impax, which received approval for ANDA 078556 on July 20, 2009; and (d) Par, which entered the market on January 16, 2014 as an authorized generic version of Lanoxin.

3. Concentration in the Market for Generic Digoxin

77. As of 2002, there were eight manufacturers of digoxin tablets. However, in the years since, the number of digoxin tablet manufacturers has decreased, making the market more concentrated and ripe for collusion. Certain manufacturers have left the digoxin tablet market. Mylan, which still lists Digitek as one of its products, temporarily stopped selling digoxin tablets after a recall of its digoxin tablets in or around April 2008.²⁶ Mylan returned to the digoxin tablet market in or around early 2015.

78. Similarly, Sun experienced manufacturing difficulties around the same time as Mylan, due to issues raised by FDA relating to quality control practices at Sun's Detroit facility. In March 2009, Sun voluntarily withdrew certain lots of its digoxin tablets.

²⁶ Mylan, Institutional Products, *available at* <http://www.mylaninstitutional-usproducts.com/>.

79. On February 3, 2012, the FDA issued a Warning Letter to West-Ward regarding its failure to comply with Current Good Manufacturing Practice at its Eatontown, New Jersey facility, specifically directed to West-Ward's digoxin tablets.²⁷

80. As a result of the Warning Letter, West-Ward "voluntarily ceased manufacturing of all product lines" and temporarily ceased operations at its Eatontown facility in the beginning of 2013.²⁸ West-Ward reopened the Eatontown facility by July 2013, and resumed manufacturing digoxin tablets. However, the issues relating to the warning letter were not fully resolved until March 26, 2014.²⁹

81. Impax and Lannett were the only two manufacturers selling generic digoxin for a brief period before West-Ward's Eatontown facility reopened in the latter half of 2013. Par entered the market in January 2014 with its authorized generic version of Lanoxin. Mylan re-entered the market in early 2015 and Sun re-entered the market in late 2015.

82. The recent increase in the number of competitors, however, has not produced the drop in prices expected from competition for a commodity product; rather, prices have continued to remain at supracompetitive levels as a result of Defendants' unlawful conduct.

4. Generic Digoxin Prices Soar

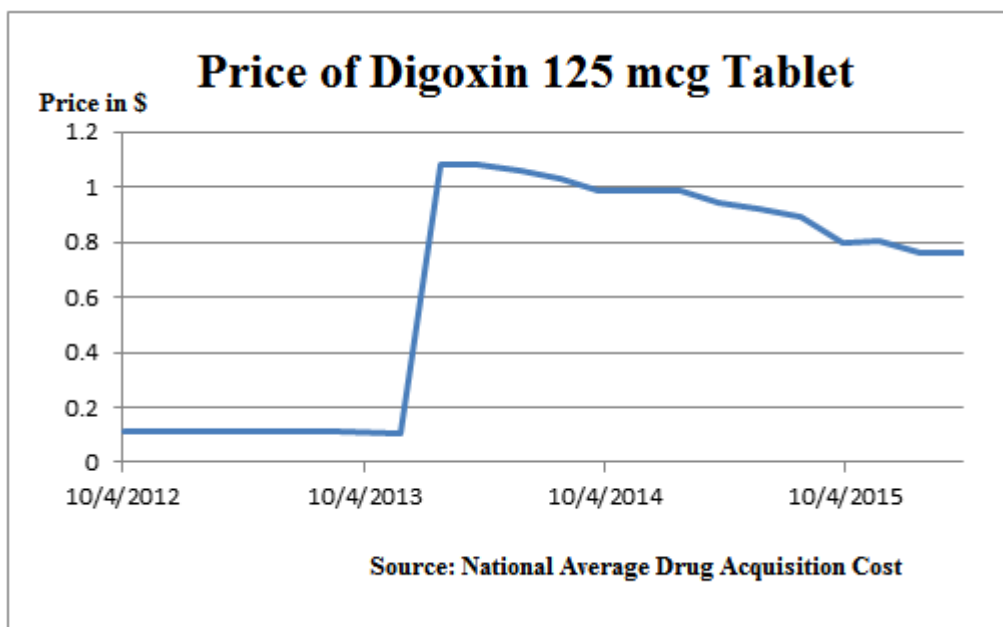
83. Until mid-October 2013, pricing of generic digoxin was stable. However, prices subsequently increased sharply without justification by Lannett, West-Ward, and Impax. This was followed by price increases by Par upon entering the market in 2014, and by Mylan upon entering the market in 2015.

²⁷ See FDA Warning Letter 12-NEJ-10 (Feb. 3, 2012).

²⁸ Hikma Annual Report 2013, at 17.

²⁹ See FDA Close-Out Letter for West-Ward (Mar. 26, 2014).

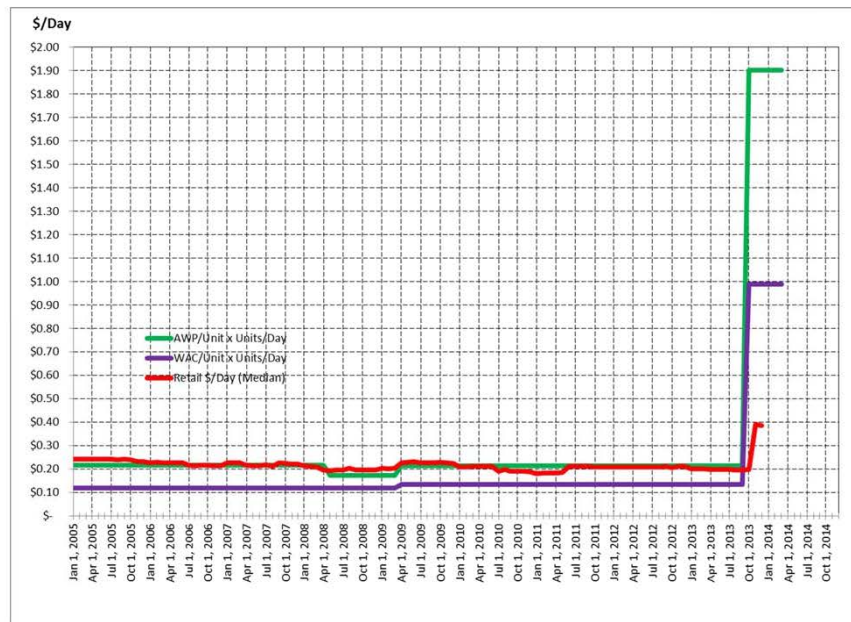
84. In or about mid-October of 2013, pricing for 0.125 mg and 0.250 mg digoxin tablets increased by more than 750% from \$0.11 and \$0.12 per tablet to \$0.91 and \$1.01 per tablet. Another price increase occurred between December 2013 and January 2014. Overall, according to National Drug Acquisition Cost (“NADAC”) Data provided by Healthcare Supply Chain Association, the average price for generic digoxin increased as much as 884% from October 2012 to June 2014.³⁰



85. As can be seen above, despite the entry of new competitors Par and Mylan to the market, the prices remained supracompetitive and did not significantly decrease. The following chart prepared by Dr. Schondelmeyer, was included in his testimony before the U.S. Senate:

³⁰ See Correspondence to Arthur P. Bedrosian, President and Chief Executive Officer of Lannett, from Senator Bernie Sanders and Congressman Elijah Cummings (Oct. 2, 2014).

Figure 12. Digoxin 0.25 mg Tablet (Lannett) Price per Day of Therapy:
(January 1, 2005 to December 31, 2013)



86. Dr. Schondelmeyer noted that generic drug prices were rising above and beyond the rate of general inflation at a rate of 12.9% versus 1.5%.³¹

87. No potential drug shortages or supply disruptions explain the price increases. Title IX of the Food and Drug Administration Safety and Innovation Act of 2012 requires mandatory drug shortage reporting for drug manufacturers. None of the Defendants reported any drug shortages or supply disruptions to the FDA that would explain the supracompetitive pricing of digoxin. Indeed, during the period of price increases, the number of competitors was increasing.

88. On July 8, 2014, the *New York Times* reported that with respect to rapid price increases of generic drugs, “[d]igoxin provides a telling case study. There was no drug shortage, according to the Food and Drug Administration, that might explain the increase. There was no new patent or new formulation. Digoxin is not hard to make. What had changed most were the financial rewards of selling an ancient, lifesaving drug and company strategies intended to reap

³¹ Schondelmeyer Statement.

the benefits.”³² Further, “[t]he three companies selling the drug in the United States had increased the price they charge pharmacies, at least nearly doubling it since late last year, according to EvaluatePharma, a London-based consulting firm.”³³

89. *Bloomberg BusinessWeek* reported that there was a ten-fold increase in the price of a three-month supply of digoxin tablets at one pharmacy in Sioux City, Iowa. Another pharmacist, speaking more generally about the sudden rise in the prices of generic drugs, stated that while sharp price increases “happened with the occasional individual drug, when there is a shortage or something,” he has “never seen it like this—with a whole range of medications where the price spikes overnight.”³⁴

90. More recently, another pharmacist testifying before Congress stated that the price of a patient’s digoxin prescription “jumped from about \$15 for 90 days’ supply, to about \$120 for 90 days’ supply.”³⁵

91. The timing of these exorbitant price increases was no accident. The market was down to a few players, thus allowing the opportunity for Defendants to conspire to raise the prices of digoxin tablets. This opportunism was reflected in the words of Lannett’s CEO, Arthur

³² Elisabeth Rosenthal, *Rapid Price Increases for Some Generic Drugs Catch Users by Surprise*, NEW YORK TIMES (July 8, 2014) available at http://www.nytimes.com/2014/07/09/health/some-generic-drug-prices-are-soaring.html?_r=0.

³³ *Id.*

³⁴ Alan Katz, *Surprise! Generic-Drug Prices Spike*, BLOOMBERG BUSINESSWEEK (Dec. 12, 2013), available at <http://www.bloomberg.com/news/articles/2013-12-12/generic-drug-prices-spike-in-pharmaceutical-market-surprise>.

³⁵ Statement of Rob Frankil before the Senate Committee on Health, Education, Labor and Pensions (HELP), *Why Are Some Generic Drugs Skyrocketing in Price?* (Nov. 20, 2014), available at <http://www.help.senate.gov/imo/media/doc/Frankil.pdf>.

Bedrosian, who was leading a charge for the generic industry to raise prices and who boasted to investors that “[w]e are an opportunistic company. We see opportunities to raise prices.”³⁶

92. At all times during the Class Period, there were three or more separate manufacturers of generic digoxin. Under the well-accepted economics of generic competition, when there are that many generic versions of a drug available, all of which by definition are equally substitutable and essentially commodities, prices should remain at highly competitive, historic levels, and would not increase as they did here, absent anticompetitive conduct.

93. Although Lannett claimed that factors influencing price increases included “problems acquiring raw material, increased costs of complying with Food and Drug Administration requirements and manufacturers exiting the market,”³⁷ these purported justifications were pretextual.

94. On a recent Concordia earnings call (Concordia holds the branded version of Digoxin), Concordia’s Executive Vice President Edward Borkowski noted that the digoxin market is “fairly mature” and that Concordia was “quite happy with the performance that our AG [authorized generic] partner [Par] has had,” but was unable to explain the market factors behind digoxin price increases.

D. Defendants’ Coordination and Collusion on Generic Drug Pricing

95. There is no market-based reason for the large increases in digoxin or doxycycline prices, such as increased costs in connection with the production of these products.

96. These price increases were dramatic, abrupt, and unprecedented departures from the pricing that had prevailed in the market in the preceding decade.

³⁶ Kevin Dobbs, *Lannett Co. Gets Growth Rx In Generic Drug Group*, Investor's Business Daily (Oct, 27, 2014), available at <http://www.investors.com/research/the-new-america/lannett-company-sees-room-to-grow-in-hot-generic-drugs-group/>.

³⁷ *Id.*

97. The Defendants are all manufacturers of digoxin and/or doxycycline, and other generic products:

| Defendant | Digoxin | Doxycycline |
|-----------|---------|-------------|
| Allergan | | X |
| Impax | X | X |
| Lannett | X | X |
| Mylan | X | X |
| Par | X | X |
| Sun | X | X |
| West-Ward | X | X |

98. Defendants sustained their supracompetitive profits by conspiring to fix, raise, maintain, and stabilize the prices of doxycycline, digoxin, and other generic tablets, and allocate markets and customers for those products. The price increases were the product of Defendants' shared desire to extract monopoly rents from captive drug purchasers.

99. As explained by one market analyst:

A plausible explanation [for rapid generic price increases] is that generic manufacturers, having fallen to near historic low levels of financial performance are cooperating to raise the prices of products whose characteristics – low sales due to either very low prices or very low volumes – accommodate price inflation. . . . All of the manufacturers – large or small – appear to be participating in the [price] inflation.³⁸

100. Defendants' statements in public investor calls and other public communications were part of the conspiracy to fix and increase generic drug prices and maintaining them at

³⁸ Ed Silverman, *Generic Drug Prices Keep Rising, but is a Slowdown Coming?*, WALL STREET JOURNAL (Apr. 22, 2015) (discussing analyst report by Sector & Sovereign Research), available at <http://blogs.wsj.com/pharmalot/2015/04/22/generic-drug-prices-keep-rising-but-is-a-slowdown-coming/>.

supracompetitive levels. Defendants are sophisticated entities and each monitors the other's statements to investors.

101. On September 10, 2013, Lannett's CEO, Arthur P. Bedrosian, stated in a fourth quarter earnings call that Lannett was leading the way with price increases and invited other generics to join Lannett in raising prices and avoid trying to steal market share from one another based on pricing:

We're not a price follower. We tend to be a price leader on price increasing and the credit goes to my sales vice president. He takes an aggressive stance towards raising prices. He understands one of his goals, his objectives as a sales vice president is to increase profit margins for the company. And he's the first step in that process. I can reduce costs and manufacturing efficiencies, but it has to be combined with sales increase, a profit increase, as I should say, by the salespeople. And he's done a good job there. With 1 or 2 exceptions, we've tended to lead in the way of price increases. We believe that these prices are important. We need to try raising them. Sometimes, it doesn't stick and we have to go back and reduce our price, and other times it does. I am finding a climate out there has changed dramatically and I see more price increases coming from our competing - competitors than I've seen in the past. And we're going to continue to lead. We have more price increases planned for this year within our budget. And hopefully our competitors will follow suit. If they don't, that's their issue. But our plan is to raise prices on any product that we think we can or we haven't raised a price.³⁹

102. Mr. Bedrosian further described his expectation that other generics would also raise prices. After citing costs applicable to all generic firms, he stated that "I would expect that all the companies are not going to behave like they have in the past. And I suspect you're going to see more price increases in the generic marketplace or certainly less price erosion in the marketplace because of that."

103. In addition Mr. Bedrosian noted, "I'm always grateful to see responsible generic drug companies realize that our cost of doing business is going up as well . . . [s]o whenever people start acting responsibly and raise prices as opposed to the typical spiral down of generic

³⁹ Lannett Q4 2013 Earnings Call Transcript (Sept. 10, 2013).

drug prices, I'm grateful. Because Lannett tends to be active in raising prices. We believe we have to sell our products for a price that we can make profit. . . . So I'm grateful to see price increases."

104. Three days later, Sun provided its assurance that it was committed to the industry-wide plan as stated by Lannett to keep prices at supracompetitive levels and not compete on price. On September 13, 2013, after Sun reported that its subsidiary URL "had undertaken price hikes in March" Sun noted that much of its FY 2014 revenue "\$60-80 million (of \$128 million in total revenue for URL estimated for FY[20]14)" would come from doxycycline,⁴⁰ affirming its intent to maintain its price increases.

105. Impax also accepted Lannett's invitation. On November 4, 2013, the then President of Impax, Carole Ben-Maimon, acknowledged that Impax had increased the price of digoxin after Lannett had increased its price, and, after noting its medical necessity to patients. In response to a question concerning Impax's "huge price increase on digoxin following Lannett's pricing action," Ms. Ben-Maimon stated: "The price increase on dig[oxin] speaks for itself, but clearly, as a medically necessary drug, our focus there is really just to make sure that a high-quality product is available to the customer."⁴¹ Ms. Ben-Maimon's comments make clear that Impax had no intention of competing for market share in the digoxin market by offering lower prices, it simply would ensure there was sufficient supply, at its newly increased pricing for its customers.

106. On November 7, 2013, on Lannett's first quarter 2014 earnings call, Mr. Bedrosian was confident enough that its price increases would hold to increase Lannett's next

⁴⁰ Ujjval Jauhari, *Sun Pharma's prospects remain bright*, BUSINESS STANDARD (Sept. 12, 2013), available at http://www.business-standard.com/article/markets/sun-pharma-s-prospects-remain-bright-113091200894_1.html.

⁴¹ Impax Q4 2013 Earnings Call Transcript (Nov. 4, 2013).

quarter guidance stating, “The primary drivers for our outstanding first quarter performance was a combination of strong sales of existing products, a favorable product mix and price increases on key products. I’m pleased to report that we believe these positive trends will continue throughout fiscal 2014. Accordingly, we have raised our guidance for fiscal 2014.”⁴² Mr. Bedrosian reiterated Lannett’s “Increase in the guidance, probably a significant portion is the price increases that we’ve talked about previously that have now really hit us in a beneficial way.” Mr. Bedrosian indicated that he believed Lannett’s growth margin was sustainable, notwithstanding the fact that they are in a commodity market, reflecting confidence that his competitors were committed to the conspiracy and would hold to their higher prices, “I would believe they are sustainable because we’re not expecting any changes that we anticipate at this point. But we’re in the commodity business, so it’s always hard to determine point when you’re going to get additional competition or when prices will erode as they generally do.” Mr. Bedrosian also indicated that the price increases were industry-wide and that he believed that all generic companies would continue to adhere to higher prices: “So these price increases that are going on in the industry, I think they’re going to stick for all the companies.”

107. Par provided its assurance that it was on board with Lannett’s plan. Despite being a new entrant and knowing that there was at least one other entrant on the horizon, Par priced its digoxin product comparably to Lannett’s and Impax’s. When it launched in January 2014, Mr. Bedrosian lauded Par’s commitment to the scheme to keep prices high stating that he viewed Par to be “one of our rational competitors in the marketplace.”⁴³

108. Not surprisingly, Lannett’s sales reported in February 2014 were the best in the company’s history. As predicted in November 2013, Mr. Bedrosian reported that these record

⁴² Lannett Q1 2014 Earnings Call Transcript (Nov. 7, 2013)

⁴³ Lannett Q2 2014 Earnings Call Transcript (Feb. 6, 2014).

sales were driven by “price increases on key products, strong sales of existing products and favorable product mix.”⁴⁴ Lannett’s stellar performance is not reflective of a company that took price increases that were forced by rising costs, but instead is reflective of a company that was enjoying the fruits of supracompetitive prices and stifling of competition. On the same call, Lannett’s CFO Martin P. Galvan also mentioned that prices were increasing across many different generic products, “But I must say that we have been able to increase prices on more than just those two products and it’s the portfolio of products and their price increases which is driving that gross margin you see.”

109. Impax’s Carole Ben-Maimon demonstrated Impax’s continued acceptance of Lannett’s invitation to increase prices and noted Impax’s commitment to maintaining price increases during a February 2014 call with analysts. Ms. Ben-Maimon stated regarding digoxin, “the market has been pretty stable with [Lannett] and us . . . [w]e’re pretty comfortable that what we have done is rational and will result in ongoing profitability for that product.”⁴⁵

110. On March 12, 2014, Hikma, West-Ward’s parent, announced strong revenue growth, driven in part by doxycycline sales, and forecasting continued growth in 2014, which would reflect continued commitment to maintaining its doxycycline pricing.⁴⁶ Mr. Darwazah, Hikma’s CEO was “confident about the prospects for 2014,” and noted that in 2013, “Our Generics business delivered very strong revenue, driven primarily by doxycycline, and generated significant cash flow.”⁴⁷

⁴⁴ *Id.*

⁴⁵ Impax Laboratories Earnings Conference Call Transcript (Feb. 20, 2014).

⁴⁶ Press Release, Hikma Pharmaceuticals plc (Mar. 12, 2014).

⁴⁷ *Id.* Hikma anticipated potentially reduced doxycycline revenue in the U.S. market in 2014 due to increased competition.

111. In a Lannett quarterly earnings call held on November 3, 2014, Mr. Bedrosian again expressed confidence that Lannett would not have to engage in price competition generally in the generic drug market and made clear Lannett's further commitment to raising and maintaining prices. Speaking about Lannett and its generic competitors, Mr. Bedrosian said, "So from my perspective, what we're seeing here is an opportunity to raise prices because everybody has accepted the fact that our costs are going up dramatically and less concerned about grabbing market share. We're all interested in making a profit, not how many units we sell."⁴⁸ Mr. Bedrosian's comment on cost increases was nothing more than a pretextual justification for the higher prices. Mr. Bedrosian further offered that Lannett was not always the price leader and that sometimes other generic companies took the lead in increasing prices: "We look at the market and sometimes we're the first ones to raise a price, sometimes we're not. But we look at everything in line as a potential product to have a price increased on." Mr. Bedrosian went on to discuss, *inter alia*, Par and Impax, saying "the companies we're looking at here are not irrational players. I don't see them just going out and trying to grab market share." He also noted that Mylan was expected to enter the market, but confidently exclaimed that "but Mylan is one of those rational competitors, so we're not really expecting anything crazy from them."

112. The Chief Executive Officer of Impax, Frederick Wilson, offered similar assurances to its competitors about its commitment to increasing prices in a third quarter earnings call on November 4, 2014:

[L]et me address pricing. We really don't talk much about pricing publicly, and whether we're going for competitive reasons but surprising to say we've done what most of the other generic competitors have done, we look at opportunities, we look at how competition shifts, we look at where there may be some market movement that will allow us to take advantages on price increases and we've implemented those and we'll continue to evaluate our line product-by-product

⁴⁸ Lannett Q1 2015 Earnings Call Transcript (Nov. 3, 2014).

probably a week and monthly basis to see if there are some opportunities to participate in that practice.⁴⁹

Wilson also acknowledged the federal investigation of pricing in the pharmaceutical industry during the November 2014 earnings call.

113. On a February 4, 2015 earnings call, Mr. Bedrosian stated, in response to a question regarding the sustainability of pricing, that:

Seriously, though, with regards to the market, we've sustained these price increases now probably close to three years. . . . So I'm expecting these pricings to really sustain themselves to continue. I see people raising prices further, because the generic prices were so low, when you're 10% of the brand, that's not because the brand overpriced the product by 90%. It's because the generic marketplace has so much competition sometimes, people get desperate just to unload their inventory that they cut the prices. We don't see that kind of behavior sustainable, and we don't see it going further into the future. I think you're going to find more capital pricing, more – I'll say less competition, in a sense. You won't have price wars. You are still going to have competition, because there's a lot of generic companies in the market. I just don't see the prices eroding like they did in the past. It's really unfortunate, but what they see some significant pricing, cost increases, I should say, that are driving this.⁵⁰

114. With respect to digoxin, Mr. Bedrosian alerted the other generic suppliers that Lannett stood ready to increase prices again because there was a potential for a market disruption “that certainly could equate to a price increase for us. So I would just say stay tuned. But we're also looking to capture more market share on the Digoxin. This is an important product for us.” Mr. Bedrosian then immediately offered a warning to other generic manufacturers that they would be prepared to discipline them, “We don't want to sit by and just let our competition take away our market share.” As to the recent entrant, Par, whom he had noted was “a rational competitor”, he did not fear it would discount to Lannett's pricing, “Well, discounting to our

⁴⁹ Impax Q3 2014 Earnings Call Transcript (Nov. 4, 2014).

⁵⁰ Lannett Q2 2015 Earnings Call Transcript (Feb. 4, 2015).

price, no. We've seen their prices discounted to the brand, of course, but we're not troubled by their pricing in the marketplace. Not at all."⁵¹

115. In addition to the public statements communicating invitations to collude and signaling willingness to increase prices in concert, Defendants have had many opportunities to communicate and collude including through trade organizations. According to news reports, the *Policy and Regulatory Report* ("PaRR") obtained information regarding the investigation of generic drug companies by the DOJ. According to PaRR, the DOJ is investigating whether trade organizations are a potential vehicle for collusion between salespeople at different generic drug companies.⁵²

116. For example, the GPhA is the "leading trade association for generic drug manufacturers and distributors, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry."⁵³ GPhA was formed in 2000 from the merger of three industry trade associations: the GPhA, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

117. Current "Regular Members" of the GPhA include Defendants Impax, Mylan, Par, Sun, and West-Ward. Regular Members "are corporations, partnerships or other legal entities whose primary United States business derives the majority of its revenues from sales of (1) finished dose drugs approved via ANDAs; (2) products sold as authorized generic drugs; (3)

⁵¹ *Id.*

⁵² Eric Palmer, *Actavis gets subpoena as DOJ probe of generic pricing moves up food chain*, FiercePharma (Aug. 7, 2015), available at <http://www.fiercepharma.com/regulatory/actavis-gets-subpoena-as-doj-probe-of-generic-pricing-moves-up-food-chain>.

⁵³ Generic Pharmaceutical Association, About the Association, available at <http://www.gphaonline.org/about/the-gpha-association>.

biosimilar/ biogeneric products; or (4) DESI products.”⁵⁴ Defendants Impax and Par have representatives on GPhA’s 2016 Board of Directors. In 2012, 2013, and 2014, Defendants Impax, Mylan, and Allergan (then Actavis), were on the GPhA Board.

118. According to GPhA’s website, “GPhA member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year.” GPhA states that, “[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry and help secure the future of this vital pharmaceutical market segment. In addition, GPhA provides valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections.”

119. Representatives from Defendants attended meetings held by GPhA. The following table lists some of the GPhA meetings attended by Defendants’ employees:

| Meeting | Meeting Date and Location | Known Attendees |
|-------------------------------------|--|--|
| 2012 GPhA Annual Meeting | February 22 to 24, 2012 Orlando, Florida | Watson (now part of Allergan), Mylan, Par |
| 2012 GPhA Fall Technical Conference | October 1 to 3, 2012 Bethesda, Maryland | Actavis (now Allergan), Lannett, Impax, Mylan, Sun |
| 2013 GPhA Annual Meeting | February 20 to 22, 2013 Orlando, Florida | Actavis (now Allergan), Impax, Mylan, Par |
| 2013 GPhA Fall Technical Conference | October 28 to 30, 2013 Bethesda, Maryland | Actavis (now Allergan), Impax, Lannett, Mylan, Par, Sun |
| 2014 GPhA Annual Meeting | February 19 to 21, 2014 Orlando, Florida | Actavis (now Allergan), Impax, Mylan, Par, Sun |
| 2014 GPhA Fall Technical Conference | October 27 to 29, 2014 Bethesda, Maryland | Actavis (now Allergan), Impax, Lannett, Mylan, Par, Sun, West-Ward |

⁵⁴ Generic Pharmaceutical Association, Membership, *available at* <http://www.gphaonline.org/about/membership>.

| | | |
|------------------------|--|--|
| 2015 GPhA CMC Workshop | June 9 to 10, 2015 Bethesda, Maryland | Actavis (now Allergan), Impax, Lannett, Mylan, Par, Sun, West-Ward |
|------------------------|--|--|

E. Defendants' Claims that Rising Costs Justified the Price Increases Were Pretextual

120. Defendants often cited to increased costs to justify their collusive price increases.

121. That these justifications were pretextual is demonstrated by the fact that throughout the period, Defendants were making record or unprecedented profits from their generic products.

122. Lannett's sales reported in February 2014 were the best in the company's history, and Lannett was able to increase its profit guidance on the strength of the price increases.

123. In 2013, Hikma reported that "Strong cash flow reflects exceptional profitability of doxycycline."⁵⁵ "Sales of doxycycline generated exceptionally strong cash flows" and Hikma used some of that cash flow to help "paydown of debt of \$117 million."⁵⁶

124. In 2013 and 2014, Sun Pharma reported that its costs were stable. In its quarterly reports during that period, Sun's directors reported that the company's material cost and other expenditures as a percentage of net sales, as well as staff costs, were substantially the same or lower than the same periods in the prior year. For example, Sun reported that net sales increased 40% in fiscal year 2013 compared to 2012 even while "[m]aterial cost, as a percentage of the net sales is 18.5% which is lower as compared to the previous year."⁵⁷ Staff costs and other

⁵⁵ Hikma Pharmaceuticals plc 2013 Preliminary Results, *available at* <http://www.hikma.com/~media/Files/H/Hikma/Attachments/pdf/prel-res-pres-12032014a.pdf>.

⁵⁶ *Id.*

⁵⁷ Sun Pharma Q4 2012 Earnings Call Transcript (May 28, 2013).

expenditures were also reported to be lower in 2013.⁵⁸ Similarly, Sun reported that second quarter 2013-14 costs were also “in-line with Q2 last year.”⁵⁹

F. Government Investigations

125. As discussed above, Defendants’ conduct in generic drug pricing is the subject of federal government investigations by the U.S. Senate and DOJ, as well as a state government investigation.

1. Congressional Investigation into Generic Drug Pricing

126. On October 2, 2014, Representative Elijah E. Cummings, the Ranking Member of the House Committee on Oversight and Government Reform, and Senator Bernard Sanders, Chairman of the Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, “sent letters to 14 drug manufacturers requesting information about the escalating prices of generic drugs used to treat everything from common medical conditions to life-threatening illnesses.”⁶⁰

127. These letters were delivered to the Presidents and CEOs of the Defendants and others—including Apotex Corp., Endo Pharmaceuticals plc (now the parent company of Par), Heritage Pharmaceuticals Inc., Dr. Reddy’s Laboratories Ltd., Marathon Pharmaceuticals, LLC, Teva Pharmaceuticals Industries Ltd., and Zydus Pharmaceuticals USA Inc. seeking information about the pricing of digoxin, doxycycline, and other generic drugs.

⁵⁸ *Id.*

⁵⁹ Sun Pharma Q2 2013 Earnings Call Transcript (Nov. 14, 2013).

⁶⁰ Ranking Members Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs, *available at* <http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file>.

128. Each letter noted that, “[t]he dramatic increase in generic prices results in decreased access for patients.”⁶¹ Further, Senator Sanders and Representative Cummings published a table in connection with their letters, demonstrating the massive price increases that both doxycycline and digoxin tablets have experienced over the last few years:

| Drug | Use | Average Market Price Oct. 2013 | Average Market Price Apr. 2014 | Average Percentage Increase |
|---|--|---|---|------------------------------------|
| Digoxin (single tablet, 250 mcg) | used to treat irregular heartbeats and heart failure | \$0.11 | \$1.10 | 884% |
| Doxycycline Hydrate (bottle of 500, 100 mg tablets) | antibiotic used to treat a variety of infections | \$20.00 | \$1,849 | 8281% |

129. The Senate Subcommittee on Primary Health and Aging held a hearing on November 20, 2014. Although the President and CEO of Lannett was scheduled to attend the hearing, no one appeared on behalf of Lannett.

130. During the Senate Hearing on generic drug prices, pharmacist Rob Frankil testified on November 20, 2014 that, “it was extremely concerning when about a year ago, pharmacies began noticing a rash of dramatic price increases for many common, previously low cost generic drugs.”⁶² According to Frankil, digoxin and doxycycline were two of the generic drugs with price spikes. With respect to digoxin, Frankil stated that:

A recent example from my own experience is the price of Digoxin—a drug used to treat heart failure. The price of this medication jumped from about \$15 for 90 days’ supply, to about \$120 for 90 days’ supply. That’s an increase of 800%. One of my patients had to pay for this drug when he was in the Medicare Part D coverage gap in 2014. Last year, when in the coverage gap he paid the old price.

⁶¹ See, e.g., Letter from Sen. Bernard Sanders & Rep. Elijah E. Cummings to Arthur P. Bedrosian (Oct. 2, 2014), *available at* <http://www.sanders.senate.gov/download/letter-to-mr-bedrosian-president-and-ceo-lannett-companyinc?inline=file>.

⁶² Frankil Statement.

This year he paid the new price. Needless to say, the patient was astounded, and thought I was overcharging him. The patient called all around to try to get the medicine at the old, lower price, but to no avail. This caused him lots of stress and time, and caused us lots of stress and time in explaining the situation, reversing, and rebilling the claim. This example is typical of how these price spikes put consumers and pharmacists in a bad position, often grasping at straws for explanations. And all the while, everyone pays more, including the patient, the pharmacy, and the insurer (often the federal government).⁶³

131. Subsequent congressional hearings concerning the dramatic rise of generic drug prices were held in December 2015 and February 2016. At the U.S. Senate Special Committee on Aging's December 9, 2015 hearing, Erin D. Fox, the Director of the Drug Information Service of the University of Utah, noted the deleterious effect these drug prices have had on patient access and healthcare, stating that "[w]hen medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage."⁶⁴

132. The Senate investigation prompted the Office of Inspector General ("OIG") to launch its own generic pricing investigation. The OIG will update its review of generic drug price increases under the Medicaid drug rebate program by examining the quarterly average manufacturer prices from 2005 through 2014 to determine the extent to which the average manufacturer prices exceeded the specified inflation factor. Brand manufacturers are compelled to pay additional rebates when their drugs' average manufacturer prices increase by more than a specified inflation factor, but there is no such requirement for generic manufacturers. As part of its study, the OIG will determine the amount of additional rebates Medicaid could have recouped

⁶³ *Id.*

⁶⁴ Statement of Erin R. Fox, PharmD Director, Drug Information Service, Hearing on "*Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines*" (Dec. 9, 2015), at 7, available at http://www.aging.senate.gov/imo/media/doc/SCA_Fox_12_9_15.pdf.

if the statutory inflation factor also applied to generics. The timetable for the results of the study has not been released.

2. Federal and State Antitrust Investigations into Defendants' Generic Drug Pricing

133. Generic pricing patterns have also captured the attention of federal and state enforcement authorities in the United States. Many Defendants have received requests for information concerning their pricing of generic drugs, including doxycycline and digoxin, as well as their communications with their competitors for those drugs.

134. The DOJ opened a criminal grand jury investigation into Defendants' conduct on or about November 3, 2014. Grand jury subpoenas have been issued to at least Lannett, Impax, Allergan, Par, Mylan, Sun, and specific employees of certain Defendants.

135. Commentators have noted that the DOJ's probe is wide-ranging:

The Justice Department's subpoenas focus on sharing and exchanging of pricing information and other issues among generic drug companies. The initial subpoenas, including two senior executives, suggest that the Justice Department has specific information relating to their participation in potentially criminal conduct. It is rare for the Justice Department to open a criminal investigation with specific subpoenas for individuals, along with company-focused subpoenas. Given the breadth of such a potential cartel investigation, the Justice Department's inquiry of the generic pharmaceutical industry could be significant. The prices for a large number of generic drug prices have increased significantly over the last year. There does not appear to be any rational explanation for such increases involving a diverse set of products.

136. The fact that grand jury subpoenas were served on Defendants is indicative that they have potentially violated antitrust law. According to the DOJ's *Antitrust Division Manual*, "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution."⁶⁵ If a grand jury request memorandum is approved by the DOJ field office

⁶⁵ See *Antitrust Division Manual*, Chapter III, Section F.1 at III-82 (2015).

chief, “a grand jury request should be emailed to the ATR-CRIM-ENF [Antitrust Criminal Enforcement Division].”⁶⁶ “The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation.”⁶⁷ Then, “[t]he investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred.”⁶⁸

137. **Lannett.** In July 2014, Lannett revealed in SEC filings that it had received subpoenas from the Connecticut Attorney General. According to Lannett’s 2014 Annual Report, the Connecticut Attorney General was “investigating whether anyone engaged in any activities that resulted in (a) fixing, maintaining or controlling prices of digoxin or (b) allocating and dividing customers or territories relating to the sale of digoxin in violation of Connecticut antitrust law.”

138. Lannett’s 10-Q report dated February 6, 2015 discloses that on November 3, 2014, “the Senior Vice-President of Sales and Marketing was served with a grand jury subpoena relating to a federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act,” and that on December 5, 2014, “[t]he Company was served with a grand jury subpoena related to the federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act. The subpoena requests corporate documents from the Company relating to corporate, financial, and employee information, communications or

⁶⁶ *Id.*

⁶⁷ *Id.* at III-83.

⁶⁸ *Id.*

correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale or pricing of certain products.”

139. Lannett disclosed in its annual report for fiscal year ending June 30, 2015, that:

[T]he Company and certain affiliated individuals each were served with a grand jury subpoena relating to a federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act. The subpoenas request corporate documents of the Company relating to corporate, financial, and employee information, communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale or pricing of certain products, generally for the period of 2005 through the dates of the subpoenas.

140. *Impax*. Impax disclosed that it also received a federal grand jury subpoena requesting testimony and documents about “any communication or correspondence with any competitor about the sale of generic drugs.”⁶⁹ The scope of the subpoenas was not limited to a particular drug or a particular timeframe. The grand jury investigating the matter is empaneled in the Eastern District of Pennsylvania.

141. Later, Impax disclosed that on March 13, 2015, “the Company received a grand jury subpoena from the Justice Department requesting the production of information and documents regarding the sales, marketing, and pricing of certain generic prescription medications. In particular the Justice Department's investigation currently focuses on four generic medications: digoxin tablets, terbutaline sulfate tablets, prilocaine/lidocaine cream, and calcipotriene topical solution.”⁷⁰

142. Impax has also been served with a subpoena from the Connecticut Attorney General.⁷¹

⁶⁹ Impax Form 2015 Form 10-K at F-53.

⁷⁰ Impax Form 10-Q (filed May 11, 2015), at 46.

⁷¹ See, e.g., *id.* at 47.

143. **Par.** Par's 10-K dated March 12, 2015 states that "[o]n December 5, 2014, we received a subpoena from the Antitrust Division of the DOJ requesting documents related to communications with competitors regarding our authorized generic version of Covis's Lanoxin® (digoxin) oral tablets." Par's parent company, Endo, stated in a 10-Q for the third quarter of 2015 that, "[o]n December 5, 2014, the Company's subsidiary, Par, received a Subpoena to Testify Before Grand Jury from the Antitrust Division of the DOJ and issued by the U.S. District Court for the Eastern District of Pennsylvania. The subpoena requests documents and information focused primarily on product and pricing information relating to Par's authorized generic version of Lanoxin (digoxin) oral tablets and Par's generic doxycycline products, and on communications with competitors and other regarding those products. Par is cooperating fully with the investigation.

144. Par's parent company, Endo International plc, disclosed in its 10-Q dated May 6, 2016 that in December 2015 that it had received interrogatories and a subpoena requesting documents from the Connecticut Attorney General "regarding pricing of certain of its generic products, including Doxycycline Hyclate" and that Endo International plc is cooperating with the Connecticut Attorney General.

145. **Allergan.** Allergan's February 26, 2016 10-K for fiscal year ending December 31, 2015, disclosed that with respect to its Actavis division, "[o]n June 25, 2015, the Company received a subpoena from the U.S. Department of Justice ("DOJ"), Antitrust Division seeking information relating to the marketing and pricing of certain of the Company's generic products and communications with competitors about such products. The Company intends to cooperate fully with the DOJ's requests."

146. **Mylan.** Mylan N.V. reported in its 10-K for fiscal year ending December 31, 2015, filed on February 16, 2016, that “[o]n December 3, 2015, a subsidiary of Mylan N.V. received a subpoena from the Antitrust Division of the U.S. Department of Justice (“DOJ”) seeking information relating to the marketing, pricing, and sale of our generic Doxycycline products and any communications with competitors about such products. The Company intends to fully cooperate with DOJ’s inquiry.”

147. Mylan’s 10-K for the fiscal year ending December 31, 2015, also noted that Mylan received a similar subpoena from the Connecticut Attorney General.

148. **Sun.** On May 28, 2016, Sun disclosed that it had received a DOJ subpoena related to Sun’s pricing and marketing of generic drugs in the United States.⁷²

149. The Department of Justice investigation of Defendants’ alleged price-fixing conduct in the generic drug industry is ongoing. Further, according to public reports, the DOJ’s criminal probe is focusing on trade associations, including GPhA, because these trade associations may have been used by Defendants’ representatives to coordinate and implement their anticompetitive scheme. Certain of Defendants’ representatives held senior positions at the GPhA, including Mylan’s Heather Bresch, Impax’s Marcy MacDonald, Par’s Tony Pera, and Sun’s Jim Kedrowski. Upon information and belief, representatives from Defendants attended meetings held by GPhA and discussed their anticompetitive schemes to raise, maintain, and stabilize the prices of doxycycline and digoxin tablets.

VI. THE GENERIC DRUG MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION

150. The factors necessary to show that a market is susceptible to collusion are present in this case:

⁷² *India’s Sun Pharma Gets Subpoena Over Generic Drug Pricing*, FORTUNE (May 28, 2016), available at <http://fortune.com/2016/05/28/sun-pharma-drug-price-subpoena/>.

(1) **High Degree of Industry Concentration:** As discussed above, a small number of competitors control a significant market share for generic digoxin, generic doxycycline, and other generic drug products.

(2) **Barriers to Entry:** Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry in the generic drug market. As noted above, it cost West-Ward tens of millions of dollars to bring its New Jersey production facility into compliance. Barriers to entry increase the market's susceptibility to a coordinated effort among the dominant entities in the generic drug industry to maintain supracompetitive prices.

(3) **Demand Inelasticity:** Generic digoxin and generic doxycycline are necessary treatment for millions of patients. Both generic digoxin and generic doxycycline are on the WHO's list of essential medicines.

(4) **Lack of Substitutes:** Many patients are unable to substitute other medications for generic digoxin and generic doxycycline. Generic digoxin is the only effective treatment for some heart patients and generic doxycycline is widely prescribed for a variety of bacterial infections and, in some cases, is the only effective treatment.

(5) **High Degree of Interchangeability:** Defendants' generic digoxin products are interchangeable, as are their generic doxycycline products, as they contain the same chemical compounds made from the same raw materials. Thus, generic digoxin and generic doxycycline are standardized across suppliers and are highly interchangeable from one Defendant to the next. Lannett's CEO, Mr. Bedrosian, has admitted the commodity nature of Lannett's generic business.⁷³

(6) **Absence of Competitive Sellers:** Defendants have increased prices despite the entry of suppliers to the market. Further, Defendants have maintained supracompetitive pricing for generic digoxin and generic doxycycline throughout the Class Period. Thus, Defendants have oligopolistic market power in the generic digoxin and generic doxycycline markets, which enables Defendants to increase prices without losing market share.

(7) **Opportunities for Contact and Communication Among Competitors:** As discussed above, certain Defendants are members of trade association GPhA which provides and promotes opportunities to communicate. Lannett's CEO made statements that Lannett and its competitors would not compete on price. The issuance of grand jury subpoenas to Defendants also supports the potential for communication among Defendants on the pricing of generic digoxin and generic doxycycline.

⁷³ Lannett Q1 2014 Earnings Call Transcript (Nov. 7, 2013).

VII. CLASS ACTION ALLEGATIONS

151. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(2) and (b)(3), Plaintiff brings this action on behalf of a Class defined as follows:

All persons or entities that directly purchased generic digoxin and/or generic doxycycline from Defendants in the United States and its territories and possessions at any time during the period October 1, 2012 until the anticompetitive effects of Defendants' conduct cease (the "Class Period").

Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

152. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class Members are numerous and widely dispersed throughout the United States. Further, the Class is readily identifiable from information and records maintained by Defendants.

153. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff's interests are not antagonistic to the claims of the other Class Members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

154. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

155. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving alleged violations of antitrust law in the pharmaceutical industry.

156. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the entire Class, thereby determining damages with respect to the

Class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

157. The common legal and factual questions, which do not vary from Class Member to Class Member and which may be determined without reference to individual circumstances of any Class Member, include, but are not limited to, the following:

- (a) Whether Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate competition and thereby artificially increase the prices of generic digoxin and generic doxycycline in the United States;
- (b) The duration and extent of the alleged contract, combination, or conspiracy;
- (c) Whether Defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;
- (d) The effect of the contract, combination, or conspiracy on the prices of generic digoxin and generic doxycycline in the United States during the Class Period;
- (e) Whether Defendants' conduct caused supracompetitive prices for generic digoxin and generic doxycycline;
- (f) Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiff and other members of the Class; and
- (g) Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

158. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual

actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

159. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VIII. ANTITRUST INJURY

160. During the Class Period, Plaintiff and Class Members directly purchased generic digoxin and generic doxycycline from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for generic digoxin and generic doxycycline than they would have and thus suffered substantial damages. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

161. Because Defendants' unlawful conduct has successfully eliminated competition in the market, and Plaintiff and Class Members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such damages will be calculated after discovery and upon proof at trial.

162. Defendants' misconduct reduced competition in the generic digoxin and generic doxycycline market, reduced choice for purchasers, and caused injury to purchasers.

163. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class continue to pay supracompetitive prices for generic digoxin and generic doxycycline.

IX. CLAIM FOR RELIEF

VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1

164. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

165. Defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

166. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

167. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Defendants entered into agreements with one another on the pricing of generic digoxin and generic doxycycline in the United States. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

168. Each Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.

169. The conspiracy had its intended effect, as Defendants benefited from their collusion and the elimination of competition, both of which artificially inflated the prices of generic digoxin and generic doxycycline, as described herein.

170. As a result of Defendants' unlawful conduct, Plaintiff and Class Members have been injured in their business and property in that they have paid more for generic digoxin and generic doxycycline than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.

171. Defendants' unlawful conduct as alleged herein poses a significant, continuing threat of antitrust injury for which injunctive relief is appropriate under Section 16 of the Clayton Act.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Class Members pray for relief as set forth below:

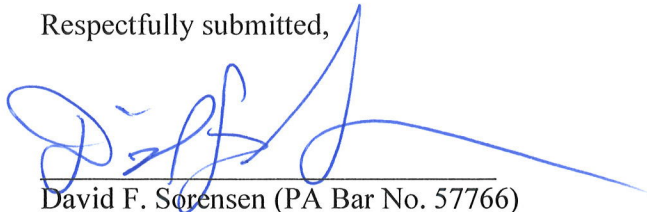
- A. Certification of the action as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;
- B. Permanent injunctive relief that enjoins Defendants from violating the antitrust laws and requires them to take affirmative steps to dissipate the effects of the violations;
- C. That acts alleged herein be adjudged and decreed to be unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;
- D. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiff and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;
- E. By awarding Plaintiff and Class Members pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the Complaint in this action;
- F. The costs of this suit, including reasonable attorney fees; and
- G. Such other and further relief as the Court deems just and proper.

XI. DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

Dated: June 20, 2016

Respectfully submitted,



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